

REMARKS

Applicants gratefully acknowledge the in-person interview conducted with Examiner Oropeza on April 22, 2008. During the interview, Applicants' representative described what they believe to be the distinguishing features of the claimed invention over the cited prior art, particularly Easterbrook et al., Kung et al. and Tsitlik et al. Among other things, Applicants emphasized the compliant nature of the cup of the cardiac assist device claimed, as well as the continuous annular cavity surrounding the apex and ventricular regions of the heart in a continuous fashion thereby effecting a more uniform pressure on the exterior of the heart, particularly that portion corresponding to the left and right ventricles.

As a result of the interview, it was agreed that Applicants would recast the claims to more particularly identify and recite those features. The Examiner encouraged Applicants to bear in mind the previous restriction/election requirement. Applicants have now recast those claims, and present them here for further examination. It is Applicants' position that the claims now presented are directed to substantially the same invention, albeit necessarily of different scope. Accordingly, Applicants submit that the claims do not run afoul of their previous election, but take this opportunity to suggest that the former restriction requirement may no longer apply and that, more so than in the past, rejoinder of at least some of the withdrawn claims is now appropriate.

Among the various changes, Applicants have recast the claims as directed to a method of treating a patient as opposed to the former preamble directed to method of assisting the function of the heart.

Support for the restructured claims is found throughout the specification.

Some of the specific terms and supporting disclosure is identified below. The preamble as it now stands is supported throughout the specification, and particularly at paragraph 0003 of the section entitled Background of the Invention (all references are to the published application US 2004/0267086 A1). Further support is found in paragraph 0004 referencing a number of mechanical techniques "for assisting heart function" by compressing the epicardial surface of the heart. Still further support is found at paragraph 0057 describing an object of the invention as providing a "Direct Mechanical Ventricular Assist device that provides a healing environment within the body of the patient, including the heart itself."

Reference to the treatment involving heart therapy can be found at, e.g., paragraph 0211, 0325, 0328, 0470, and elsewhere in the specification both explicitly and implicitly.

In paragraph 0009, the specification refers to installing the cup on the heart of the patient. Such installation results in connecting the cardiac assist device to the patient. Likewise, at paragraph 0051, the specification refers to installing the cup of the device of the present invention in short order in the patient. In addition, the specification repeatedly refers to the installation of the device wherein the cup is installed over at least a portion of the heart. See, e.g., paragraphs 0009, 0051, 0053, 0054 and 0077, and elsewhere within the specification.

Support for the compliant cup and its conformability throughout dynamic actuation of the heart can be found at, e.g., paragraphs 0540, 0541, 0043, and 0139, as well as elsewhere throughout the specification.

Reference to the annular cavity formed by the cup structure of the cardiac assist device is found at, e.g., the abstract and at paragraph 0305.

Other recited elements of the claim are substantially consistent with elements in the prior iteration of claim 131, and thus are not detailed here.

As discussed during the in person interview, the present invention is distinguishable over Easterbrook in that Easterbrook describes a cuff-like structure that does not form a continuous annular cavity completely surrounding the apex and/or ventricular region of the heart. Rather, Easterbrook describes a device that is sealed on four sides thereby forming a sealed cubic or pillow-shaped object, albeit one capable of being wrapped around the heart. The Easterbrook device does not represent a continuous annular cavity completely surrounding the ventricular portions of the heart.

Likewise, the Tsitlik reference does not teach or suggest the instantly claimed invention. Rather Tsitlik describes a mechanical structure said to be useful in assisting the function of the heart but one that is of fixed and constant exterior dimension. That is, the Tsitlik reference does not satisfy the limitation of the instant claims of being compliant and capable of conforming to the heart throughout the dynamic structural changes associated with systolic and diastolic actuation.

The conformable nature of the claimed invention affords several advantages. Among these are the ability to introduce the cup of the recited device through a small incision in the rib cage thereby reducing trauma to the patient and facilitating widespread application in less controlled environments. The compliant nature of the cup facilitates rapid installation of the device without requiring a surgeon, an operating room, or traumatic surgical procedures.

Additionally, the compliant nature of the cup of the recited device means that the device will dynamically conform to the heart throughout systolic and diastolic actuation, both through the action of the liner and the exterior structural wall element of the cup. The instant cup, affording such conformability, will, among other things, reduce abrasion on the exterior wall of the heart as where the action and motion of the heart exceeds the dynamic capacity of a less compliant structure. Accordingly, the compliant structure recited herein thus maintains closer contact with the heart, affording a reliable vacuum seal between cup and heart, more constant contact with the exterior wall of the heart, more accurate and consistent monitoring capacity, and other such advantages.

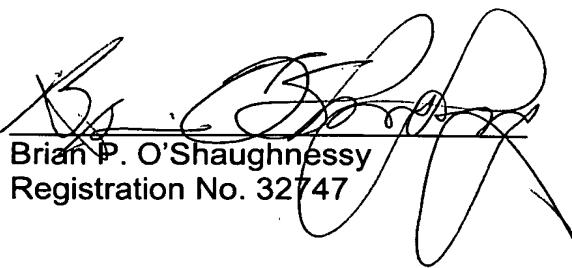
In view of the foregoing amendments and remarks, applicants respectfully request reconsideration and withdrawal of all outstanding rejections. Applicants submit that the claims are now in condition for allowance, and respectfully request formal notification to that effect. If, however, the Examiner perceives any impediments to such a notice of allowability, whether substantive or formal, the Examiner is encouraged to call Applicants' attorney at the number provided below. Such informal communication will expedite examination and disposition of this case.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: 4-29-08

By:


Brian P. O'Shaughnessy
Registration No. 32747

P.O. Box 1404
Alexandria, VA 22313-1404
703 836 6620